International Standard

ISO 33401

Reference materials — Contents of certificates, labels and accompanying documentation

Matériaux de référence — Contenu des certificats, des étiquettes et de la documentation d'accompagnement

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 334, *Reference materials*.

This first edition of ISO 33401 cancels and replaces ISO Guide 31:2015, which has been technically revised.

The main changes are as follows:

— transformation from a Guide to an International Standard;

— addition of requirements for product information sheets and revision of Table 1 accordingly;

— editorial changes for clarification.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Reference materials (RMs) are essential for quality assurance in various fields of measurement. RMs are used in diverse measurement processes, including calibration, quality control, proficiency testing and method validation.

Users of RMs obtain the information necessary for their proper use through the documentation that accompanies RMs. Therefore, standardization is required for the content and format of RM documentation. In response to growing needs, the ISO Committee on Reference Materials (ISO/REMCO) published the first, second and third editions of ISO Guide 31 in 1981, 2000 and 2015, respectively. The first edition of ISO Guide 31 discussed the difference between the information provided on the label, the certificate and the certification report, and stressed the brief synoptic nature of the certificate. The second edition focused on the required content of the certificate of a certified reference material (CRM). The third edition introduced the concepts of a "product information sheet" and a "reference material certificate" and described the information that should be included in these RM documents.

Having assumed the responsibilities of ISO/REMCO, ISO/TC 334 publishes this first edition of ISO 33401, which largely follows the third edition of ISO Guide 31. This document is intended to be complementary to ISO 17034 and provides support for the implementation of ISO 17034 on the requirements for RM documentation.

In this document, the term "certification" refers to the certification of RMs.

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